DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 16, 2015

Quest Medical Imaging
Mr. Martin Heuvelmans
Quality Assurance Manager
Industrieweg 41
1775 PW Middenmeer
Netherlands

Re: K141164
Trade/Device Name: Artemis Light Engine
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NTN
Dated: February 13, 2015
Received: February 13, 2015

Dear Mr. Heuvelmans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141164

Device Name

Artemis Light Engine

Indications for Use *(Describe)*

The Artemis Light Engine is a primary LED light source when used in conjunction with laparoscopes or surgical cameras to illuminated surgical sites that allow observation or manipulation of body cavities, hollow organs, and canals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary (21 CFR 807.92(c))

Administrative information

Manufacturer Name: Quest Medical Imaging
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1775 PW Middenmeer
Netherlands

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FDA Establishment Registration Number: 3010590422

Date prepared: March 3, 2014

Name of Device:
Trade Name: Artemis Light Engine
Common Name: LED light source
Classification Name: 21 CFR 876.1500
Product Code: NTN

Identification of Predicate Device(s):

510(k) Number	**Device**	**Manufacturer**
K130819	CLLV1, LED Light Source	Olympus Winter & Ibe GmbH
K123956	Power LED 175	Karl Storz GmbH & Co. KG

Intended Use Statement
The Artemis Light Engine is a primary LED light source when used in conjunction with laparoscopes or surgical cameras to illuminated surgical sites that allow observation or manipulation of body cavities, hollow organs, and canals.

Device description
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The Light Engine is a family of light engines that are designed for laboratory and clinical use in applications. The Light Engine provides a light source of which the

intensity can be controlled via a PC. The output power of the Light Engine is calibrated as to provide a linear response over the full range of intensity and life-time. The Light Engine can be controlled by an external software device, or directly with the serial port provided by the USB interface (RS232-via-USB).

Performance Testing
The performance testing to verify light output of the Artemis Light Engine was done as per the Bench Testing protocol attached. Design Test and Verification demonstrates that the device functions as it is intended and its performance does not raise any issues of safety and effectiveness. Software verification testing was successfully performed and completed. The manufacturer complies with the following voluntary standards:

- IEC 60601-1-2 Edition 3: 2007-03 Medical Electrical Equipment Part1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements And Tests.
- ISO 14971 Second edition 2007-03-01, Medical Devices – Application of Risk Management to Medical Devices.

Predicate Device Comparison
The Artemis Light Engine is substantially equivalent to the above listed 510(k) cleared devices on the market. Wording differences between indications for use of the Artemis Light Engine and those of the above-listed predicate devices do not constitute a new intended use. The characteristics and technology used are comparable with the predicate devices.

Conclusions
The Artemis Light Engine has similar intended use and technical features as the predicate devices listed above. Therefore, the Artemis Light Engine is substantially equivalent to the predicate devices listed above.